Reports of Cases

JUDGMENT OF THE COURT (First Chamber)

14 October 2021 *

(Reference for a preliminary ruling – Regulation (UE) No 528/2012 – Article 3(1)(a) and (c) – Definitions of 'biocidal product' and 'active substance' – Conditions – Mode of action other than mere physical or mechanical action – Article 9(1)(a) – Approval of an active substance – Scope of approval)

In Case C-29/20,

REQUEST for a preliminary ruling under Article 267 TFEU from the Oberlandesgericht Köln (Higher Regional Court, Cologne, Germany), made by decision of 10 January 2020, received at the Court on 23 January 2020, in the proceedings

Biofa AG

v

Sikma D. Vertriebs GmbH und Co. KG,

THE COURT (First Chamber),

composed of L. Bay Larsen (Rapporteur), Vice-President of the Court, acting as President of the First Chamber, N. Jääskinen and J.-C. Bonichot, Judges,

Advocate General: A. Rantos,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

– Biofa AG, by C. Stallberg, Rechtsanwalt,

– Sikma D. Vertriebs GmbH und Co. KG, by B. Münster, Rechtsanwalt,

– the European Commission, by R. Lindenthal and M. Noll-Ehlers, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 20 May 2021,

* Language of the case: German.

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 3(1)(a) and Article 9(1)(a) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ 2012 L 167, p. 1), as amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 (OJ 2014 L 103, p. 22) ('Regulation No 528/2012').

2 The request has been made in proceedings between Biofa AG, a company which develops and markets biocidal products, and Sikma D. Vertriebs GmbH und Co. KG ('Sikma'), an online retailer of pest-control products, concerning the marketing by Sikma of products containing an active substance which has been approved and is intended for use in biocidal products.

Legal context

European Union law

Regulation No 528/2012

3 Recitals 1, 3 and 9 of Regulation No 528/2012 is worded as follows:

'(1) Biocidal products are necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured materials. However, biocidal products can pose risks to humans, animals and the environment due to their intrinsic properties and associated use patterns.

…

(3) … This Regulation should be underpinned by the precautionary principle to ensure that the manufacturing and making available on the market of active substances and biocidal products do not result in harmful effects on human or animal health or unacceptable effects on the environment. …

…

(9) This Regulation should apply to biocidal products that, in the form in which they are supplied to the user, consist of, contain or generate one or more active substances.'

4 Article 1 of that regulation, entitled 'Purpose and subject matter', provides:

'1. The purpose of this Regulation is to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment. The provisions of this Regulation are underpinned by the precautionary principle,

the aim of which is to safeguard the health of humans, the health of animals and the environment. …

2. This Regulation lays down rules for:

(a) the establishment at Union level of a list of active substances which may be used in biocidal products;

(b) the authorisation of biocidal products;

…

(d) the making available on the market and the use of biocidal products within one or more Member States or the Union;

…’

5 Article 3 of that regulation, entitled ‘Definitions’, provides in paragraphs 1 and 3:

‘1. For the purposes of this Regulation, the following definitions shall apply:

(a) “biocidal product” means

– any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,

…

(c) “active substance” means a substance or a micro-organism that has an action on or against harmful organisms;

…

(g) “harmful organism” means an organism, including pathogenic agents, which has an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, on animals or the environment;

…

(x) “Agency” means the European Chemicals Agency established by Regulation (EC) No 1907/2006 [of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1)];

…

3. The Commission may, at the request of a Member State, decide, by means of implementing acts, … whether a specific product or group of products is a biocidal product or a treated article or neither. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).'

6 Article 4 of that regulation, entitled 'Conditions for approval', provides, in paragraph 1:

'An active substance shall be approved for an initial period not exceeding 10 years if at least one biocidal product containing that active substance may be expected to meet the criteria laid down in point (b) of Article 19(1) taking into account the factors set out in Article 19(2) and (5). …'

7 Article 6 of Regulation No 528/2012, entitled 'Data requirements for an application', provides in paragraph 1:

'An application for approval of an active substance shall contain at least the following elements:

(a) a dossier for the active substance satisfying the requirements set out in Annex II;

(b) a dossier satisfying the requirements set out in Annex III for at least one representative biocidal product that contains the active substance; …

…'

8 Under Article 9 of that regulation, entitled 'Approval of an active substance':

'1. The Commission shall, on receipt of the opinion of the Agency referred to in Article 8(4), either:

(a) adopt an implementing Regulation providing that an active substance is approved, and under which conditions, including the dates of approval and of expiry of the approval; …

…

2. Approved active substances shall be included in a Union list of approved active substances. The Commission shall keep the list up to date and make it electronically available to the public.'

9 Article 19 of that regulation, entitled 'Conditions for granting an authorisation', provides in paragraph 1:

'A biocidal product other than those eligible for the simplified authorisation procedure in accordance with Article 25 shall be authorised provided the following conditions are met:

(a) the active substances are approved for the relevant product-type and any conditions specified for those active substances are met;

…'

10 Article 95 of that regulation entitled 'Transitional measures concerning access to the active substance dossier' provides in paragraphs 1 and 2:

'1. As of 1 September 2013, the Agency shall make publicly available and shall regularly update a list of all active substances, and all substances generating an active substance, for which a dossier … has been submitted and accepted or validated by a Member State in a procedure provided for by this Regulation or that Directive … For each relevant substance, the list shall also include all persons having made such a submission …

A person established within the Union who manufactures or imports a relevant substance, on its own or in biocidal products … or who manufactures or makes available on the market a biocidal product consisting of, containing or generating that relevant substance …, may at any time submit to the Agency either a complete substance dossier for that relevant substance, a letter of access to a complete substance dossier, or a reference to a complete substance dossier for which all data protection periods have expired. …

…

2. As of 1 September 2015, a biocidal product consisting of, containing or generating a relevant substance, included in the list referred to in paragraph 1, shall not be made available on the market unless either the substance supplier or the product supplier is included in the list referred to in paragraph 1 for the product-type(s) to which the product belongs.'

Implementing Regulation (EU) 2017/794

11 Under Article 1 of Commission Implementing Regulation (EU) 2017/794 of 10 May 2017 approving silicon dioxide Kieselguhr as an existing active substance for use in biocidal products of product-type 18 (OJ 2017 L 120, p. 7):

'Silicon dioxide Kieselguhr is approved as an active substance for use in biocidal products of product-type 18, subject to the specifications and conditions set out in the Annex.'

German law

12 Under Paragraphs 3 and 3a of the Gesetz gegen den unlauteren Wettbewerb (Law against Unfair Competition, BGBl. 2010 I, p. 254), in the version applicable to the dispute in the main proceedings, infringement of a statutory provision, which seeks, inter alia, to circumscribe the behaviour of market operators on that market, constitutes a prohibited unfair commercial practice if that infringement is liable to affect appreciably the interests of consumers, other operators on the market or competitors.

The dispute in the main proceedings and the question referred for a preliminary ruling

13 Biofa, a trading company incorporated under German law, develops and markets biocidal products.

14 Under the trade name InsectoSec ®, one of those products, used to control crawling vermin in poultry houses, contains the active substance known as 'diatomaceous earth' or '*kieselguhr*' ('the active substance at issue').

15 Biofa, in accordance with Regulation No 528/2012, applied to the Commission for approval of the active substance at issue, which was granted to it by Implementing Regulation 2017/794, as an active substance intended for use in biocidal products of product-type 18, namely insecticides, acaricides and products to control other arthropods, as described in Annex V to Regulation No 528/2012, subject to the specifications and conditions set out in the annex to that regulation.

16 It is apparent from the order for reference that Biofa was entered on the list of suppliers referred to in Article 95(1) of Regulation No 528/2012. It is the only producer of that active substance.

17 Sikma, a company incorporated under German law, markets the product known as 'HS Mikrogur' which also contains the active substance at issue, but which is offered to animal owners and the food industry for the purpose of controlling mites infesting poultry.

18 Since Sikma does not obtain supplies of the active substance at issue from Biofa, Biofa brought an action before the Landgericht Köln (Regional Court, Cologne, Germany) for injunctive relief prohibiting unfair competition. In support of its action, Biofa claimed that the action of the active substance at issue contained in the product marketed by Sikma is not limited to enabling that product to fulfil its function by a mere physical or mechanical action. Therefore, that product should be classified as a 'biocidal product' within the meaning of Article 3(1)(a) of Regulation No 528/2012. Accordingly, Sikma's marketing of that product constitutes an unlawful commercial practice under national law and, moreover, infringes the provisions of that regulation.

19 According to Sikma, the product which it markets cannot be classified as a 'biocidal product' within the meaning of Article 3(1)(a) of Regulation No 528/2012, since the action of the active substance at issue is only physical or mechanical.

20 The Landgericht Köln (Regional Court, Cologne) dismissed Biofa's application. After establishing that it was required to examine whether the product marketed by Sikma falls within the definition of a 'biocidal product' as defined by that provision, that court decided, on the basis of a national expert's report, that that product was not intended to destroy, deter, render harmless or prevent the action of, or otherwise exert a controlling effect on, harmful organisms by any means other than mere physical or mechanical action and that, therefore, that product did not come under that definition.

21 On appeal against that decision of the Landgericht Köln (Regional Court, Cologne) brought by Biofa, the referring court, the Oberlandesgericht Köln (Higher Regional Court, Cologne, Germany), whilst inclined to uphold the merits of that decision, nevertheless asks whether the approval of an active substance by an implementing regulation, in accordance with Article 9 of Regulation No 528/2012, implies that the court hearing the action is required to find that the product containing that substance is a 'biocidal product' within the meaning of Article 3(1)(a) of that regulation, without that court being able to determine, where appropriate through an expert's report for that purpose, whether the conditions laid down by that provision have been met.

22 In those circumstances, the Oberlandesgericht Köln (Higher Regional Court, Cologne) decided to stay the proceedings and refer the following question to the Court of Justice for a preliminary ruling:

'Where an active substance is approved in an implementing regulation adopted pursuant to Article 9(1)(a) of Regulation … No 528/2012, can it be taken as given in court proceedings in a Member State that the substance on which the approval is based is intended, within the meaning of Article 3(1)(a) of [that regulation], [to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on harmful organisms] by any means other than mere physical or mechanical action, or is it for the adjudicating national court to establish in fact whether the preconditions for the application of Article 3(1)(a) of [that regulation] are fulfilled even after an implementing regulation has been adopted?'

Consideration of the question referred

23 By its question, the referring court asks, in essence, whether the first indent of Article 3(1)(a) of Regulation No 528/2012, read in conjunction with Article 3(1)(c) of that regulation, must be interpreted as meaning that a product intended to destroy, deter or render harmless harmful organisms, which contains an active substance approved under an implementing regulation of the Commission, in accordance with Article 9(1)(a) of that regulation, does not, solely because of that approval, come under the definition of 'biocidal product' within the meaning of the first indent of Article 3(1)(a) of that regulation, with the result that it falls to the competent national court to ascertain whether that product satisfies all the conditions laid down by that provision in order to come under that definition.

24 As a preliminary point, it should be noted that, since the question referred relates exclusively to the case of a product 'containing an active substance approved' by an implementing regulation, reference should be made to the definition of 'biocidal product' in the first indent of Article 3(1)(a) of Regulation No 528/2012, which specifically envisages such a situation.

25 Pursuant to that provision, the term 'biocidal product' covers 'any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action'.

26 It is thus apparent from the wording of the first indent of Article 3(1)(a) of Regulation No 528/2012 that a product must be classified as a 'biocidal product', within the meaning of that provision, if it satisfies three conditions. First, that product must consist of one or more 'active substances', whether because it contains those substances or because it generates them. Secondly, the product must pursue certain aims, namely destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on any harmful organism. Thirdly, the mode of action of that product must be 'other than mere physical or mechanical action'.

27 The Court has held, in that regard, that, in so far as the effect of a product results from an action 'other than mere physical or mechanical action' within the meaning of that provision, and that the other conditions laid down therein are met, that product undoubtedly falls within the scope of that provision (judgment of 19 December 2019, *Darie*, C-592/18, EU:C:2019:1140, paragraph 38).

28 It follows that the three conditions laid down in the first indent of Article 3(1)(a) of that regulation, as set out in paragraph 26 above, are cumulative, so that the presence in the product concerned of an active substance does not, in itself, have the effect of conferring on it the status of a 'biocidal product' within the meaning of that provision.

29 That being so, it must be stated that the fact that a product contains an active substance approved by a Commission implementing regulation, in accordance with Article 9(1)(a) of Regulation No 528/2012, must be regarded as a significant indication that the product in question may be regarded as a 'biocidal product' within the meaning of the first indent of Article 3(1)(a) of that regulation.

30 In that regard, it must be borne in mind that the definition of 'active substance', under Article 3(1)(c) of that regulation, covers any substance or micro-organism which has an action on or against harmful organisms. Although, unlike the mode of action specified in the first indent of Article 3(1)(a), Article 3(1)(c) does not contain any details as to the mode of action of such a substance, it must nevertheless be held, as the Advocate General observed in points 56 to 62 of his Opinion, that the mode of action, 'other than physical or mechanical', is inherent in an 'active substance' such as the one at issue in the main proceedings, which was approved in accordance with Article 4 of Regulation No 528/2012.

31 As the Commission maintained in its written observations, the mode of action of an active substance is examined during the procedure for approving an active substance. In this instance, the conditions referred to in Article 4 of Regulation No 528/2012 have been verified and, in particular, as paragraph 1 of that provision expressly provides, an active substance is to be approved only if at least one biocidal product containing that active substance is capable of satisfying the criteria for authorising biocidal products referred to in Article 19(1)(b) of that regulation.

32 In addition, Article 6(1)(a) and (b) of that regulation provides that the application for approval of an active substance must include not only 'a dossier for the active substance' itself, but also 'a dossier satisfying the requirements set out in Annex III for at least one representative biocidal product that contains the active substance'.

33 It follows that an active substance is, by definition, called upon to have 'an action on or against harmful organisms' within the meaning of Article 3(1)(c) of Regulation No 528/2012, and that that substance is approved only in so far as it is shown that it can be used to create a product that has an action on or against such organisms, other than physical or mechanical.

34 In those circumstances, it must be held that, if the composition of a given product is identical to the composition of the representative biocidal product containing the active substance, within the meaning of Article 6(1)(b) of Regulation No 528/2012, the national court hearing the case is then required to classify that product as a 'biocidal product' within the meaning of the first indent of Article 3(1)(a) of that regulation.

35 The objective of Regulation No 528/2012 confirms that interpretation. As is apparent from Article 1(1) of that regulation, read in the light of recital 3, the purpose of that regulation is to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health, and the environment, its provisions being based on the precautionary principle, the aim of which is to protect human health, animal health and the

environment. In this respect, it should be observed that, as the Court has already ruled, it is the very presence of an active substance as such in a product that is likely to present a risk to the environment (see, to that effect, judgments of 2012, *Söll*, C-420/10, EU:C:2012:111, paragraph 27, and of 19 December 2019, *Darie*, C-592/18, EU:C:2019:1140, paragraph 44).

36 It is apparent from the file before the Court that, in the present case, Biofa mentioned, in its application for approval of the active substance at issue, a representative biocidal product, composed of 100% of that active substance. It follows that, if the composition of the product marketed by Sikma is identical to the composition of the representative biocidal product, the first product must be regarded as a 'biocidal product' within the meaning of the first indent of Article 3(1)(a) of Regulation No 528/2012, and Sikma cannot validly claim that the active substance contained in its product is used exclusively to enable that product to fulfil its function by mere physical or mechanical action on or against harmful organisms.

37 Otherwise, such an assessment is a matter for the referring court.

38 In the light of the foregoing, the answer to the question referred is that the first indent of Article 3(1)(a) of Regulation No 528/2012, read in conjunction with Article 3(1)(c) of that regulation, must be interpreted as meaning that a product intended to destroy, deter or render harmless harmful organisms, which contains an active substance approved under an implementing regulation of the Commission, in accordance with Article 9(1)(a) of that regulation, does not, solely because of that approval, come under the definition of 'biocidal product' within the meaning of the first indent of Article 3(1)(a) of that regulation, with the result that it falls to the competent national court to ascertain whether that product satisfies all the conditions laid down by that provision in order to come under that definition. However, where the composition of that product is identical to the composition of the biocidal product presented as representative at the time of the application for approval of that active substance, that court is required to consider that that product comes under that definition.

Costs

39 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (First Chamber) hereby rules:

The first indent of Article 3(1)(a) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, as amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014, read in conjunction with Article 3(1)(c) of that regulation, must be interpreted as meaning that a product intended to destroy, deter or render harmless harmful organisms, which contains an active substance approved under an implementing regulation of the Commission, in accordance with Article 9(1)(a) of that regulation, does not, solely because of that approval, come under the definition of 'biocidal product' within the meaning of the first indent of Article 3(1)(a) of that regulation, with the result that it falls to the competent national court to ascertain whether that product satisfies all the conditions laid down by that provision in order to come under that definition. However, where the composition of that product is identical to

the composition of the biocidal product presented as representative at the time of the application for approval of that active substance, that court is required to consider that that product comes under that definition.

[Signatures]